Clean Copy of Claims:

Claim 9. An assay for determining the concentration of epidermal growth factor receptor in a biological sample from a human patient, the assay comprising:

a) obtaining a biological sample from the patient;

b) contacting an amount of a first purified antibody that specifically reacts with a first epitope of the extracellular ligand binding domain of sErbB1 with the patient biological sample to be tested, wherein the first purified antibody is modified with a first labeling moiety;

c) contacting the sample with an amount of a second purified antibody that specifically reacts with a second epitope of the extracellular ligand binding domain of sErbB1, wherein the second purified antibody is modified with a second labeling moiety, and wherein the second purified antibody does not competitively inhibit the binding of the first purified antibody;

d) detecting the co-presence of the first and second labels to determine the concentration of the epidermal growth factor receptor complexed with the antibodies; wherein one of the antibodies is chosen from the group consisting of: MAb R.1 and antibodies with competitively inhibit the binding of MAb R.1 to ErbB1; and wherein the other antibody is chosen from the group consisting of MAb 528 and antibodies which competitively inhibit the binding of MAb 528 to ErbB1;

e) comparing the concentration of epidermal growth factor receptor obtained in step d) with a normal value; and

f) correlating a decrease in the concentration of epidermal growth factor receptor in the patient biological sample with the presence of a carcinoma in the patient.

Claim 10: The assay of claim 9 wherein the patient biological sample is chosen from the group consisting of urine and ascites.

Claim 11: The assay of claim 9 wherein the patient biological sample is chosen from the group consisting of blood, serum and plasma.

Claim 12: The assay of claim 11 wherein the first labeling moiety is an affinity binding moiety.

Claim 13: The assay of claim 12 wherein the affinity binding moiety is biotin.

Claim 14: The assay of claim 13 wherein detection of the presence of the first labeling moiety is by binding of the biotin moiety to a solid support coated with a molecule chosen from the group consisting of streptavidin and avidin.

Claim 15: The assay of claim 9 wherein the second labelling moiety is selected from the group consisting of a fluorescent moiety, a colorigenic moiety, and a chemiluminescent moiety.

Claim 16: The assay of claim 9 wherein the second labelling moiety is acridinium.

Claim 17: The assay of claim 16 wherein the detection of the presence of the second labeling moiety is by measuring light emitted from a chemiluminescent reaction utilizing the second labeling moiety.

Claim 18: An assay for determining the concentration of epidermal growth factor receptor in a biological sample from a female patient, the assay comprising:

a) obtaining a biological sample from the female;

b) contacting an amount of a first purified antibody that specifically reacts with a first epitope of the extracellular ligand binding domain of sErbB1 with the biological sample to be tested, wherein the first purified antibody is modified with a first labeling moiety;

c) contacting the sample with an amount of a second purified antibody that specifically reacts with a second epitope of the extracellular ligand binding

domain of SerbB1, wherein the second purified antibody is modified with a second labeling moiety, and wherein the second purified antibody does not competitively inhibit the binding of the first purified antibody;

d) detecting the co-presence of the first and second labels to determine the concentration of the epidermal growth factor receptor complexed with the antibodies; wherein one of the antibodies is chosen from the group consisting of: Mab R.1 and antibodies which competitively inhibit the binding of Mab R.1 to ErbB1; and wherein the other antibody is chosen from the group consisting of Mab 528 and antibodies which competitively inhibit the binding of Mab 528 to ErbB1.

e) comparing the concentration of soluble epidermal growth factor receptor obtained in step d) with a normal value; and

f) correlating a decrease in the concentration of soluble epidermal growth factor receptor in the patient biological sample with the presence of an ovarian carcinoma in the patient.

Claim 19: The assay of claim 18 wherein the normal value is obtained by assaying biological samples from females of approximately the same age as the patient.

Claim 20: The assay of claim 18 further comprising the step of performing a second assay on a biological sample obtained from the patient at a point in time after the initial assay.

Claim 21: The assay of claim 20, wherein the patient has undergone treatment for ovarian cancer selected from the group consisting of chemotherapy, radiation therapy, and surgical treatment in the interval between the initial and second assay.

Claim 22: The assay of claim 20, further comprising the step of correlating an increase in the concentration of soluble epidermal growth factor receptor in the patient biological sample with an improved prognosis in the ovarian cancer condition.

Claim 23: The assay of claim 20, further comprising the step of correlating a decrease in the concentration of soluble epidermal growth factor receptor in the patient biological sample with an declining prognosis in the ovarian cancer condition.